DIAZYME

OCT 2 9 2004

K042193

Summary

Submitter's name: Diazyme Laboratories Division, General Atomics

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Name of Contact Person: Chong Yuan, Ph.D.
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Date the summary was prepared: July 7, 2004

Name of the device: Glycated Serum Protein Enzymatic Assay
Trade Name: Diazyme Glycated Serum Protein Enzymatic Assay
Common/Usual Name: Enzymatic Assay, Fructosamine
Classification Name: Glycosylated Hemoglobin Assay (Per 21CFR section 862.3560)
Device Class: II

Predicate Device:

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:
Randox Fructosamine (K023763) manufactured by Randox Laboratories, Ltd., Antrim, UK.

Description of the devices

Existing methods for the assay of glycated serum proteins or fructosamine such as furosine (HPLC), affinity chromatography, thiobarbituric acid (TBA) and nitroblue tetrazolium (NBT) are time consuming, difficult to automate and/or lack of specificity. Enzymatic assay of fructosamine is proven to be not only more specific and more accurate but also more user friendly for use in automated analyzers.

Diazyme's glycated serum protein (**Dia-GSP™**) assay is a specific enzymatic method for direct determination of fructosamine in serum. The assay utilizes Diazyme's proprietary frucosyl amine-oxygen oxidoreductase (fructosaminase™) to specifically react with the glycated amino acid substrates generated by on-line digestion of serum sample proteins with Proteinases. Liberation of hydrogen peroxide from the fructosaminase™ reaction allows a colorimetric determination of the amount of glycated protein through a coupled reaction with peroxidase.

Intended Use of the Device:

Diazyme Glycated Serum Protein Enzymatic Assay Kit in conjunction with Diazyme Glycated Serum Protein single calibrator, are intended for the quantitative determination of glycated serum proteins (fructosamine) in serum.

Performance Characteristics

Diazyme's Glycated Serum Protein enzymatic assay is a two reagent (R1 and R2) based end point assay system. The results are obtained in 10 min by measuring absorbance at 550 nm. No off line pretreatment is needed. The assay has a wide measuring range from 0 to 1354 μmol/L. The assay offers excellent precision as shown in the table below:

	280 μmol/L	586 μmol/L
Inter-assay Precision	CV%=1.74	CV%=1.75
Total Precision	CV%=2.87	CV%=2.94

Diazyme's Glycated Serum Protein Enzymatic assay has good correlation with Randox Fructosamine assay (correlation coefficient of 0.98). We have conducted interference study by spiking the substances to be tested to the pooled human sera and found little interference at the indicated concentrations

Interference	Concentration
Uric Acid	2 mM
Haemoglobin	200 mg/dl
Glucose	133 mM
Triglyceride	2000 mg/dl
Ascorbic Acid	0.230 mM
Bilirubin	20 mg/dl

Conclusion: Comparison analysis presented in the 510K submission for this device in the comparison section, together with linearity, precision and interference study presented demonstrated that the Diazyme's Glycated Serum Protein Enzymatic assay has excellent accuracy and is safe and effective. There is no significant deviation between the results obtained by Diazyme's Glycated Serum Protein Enzymatic assay and legally marketed predicate Randox Fructosamine when testing clinical patient serum samples. Therefore, Diazyme's Glycated Serum Protein Enzymatic assay is substantially similar to the commercially available products to measure glycated serum proteins in human serum samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 2 9 2004

Chong Yuan, Ph.D.
Managing Director
Diazyme Laboratories
Div. of General Atomics
3550 General Atomics Ct.
San Diego, CA 92121

Re: k042193
Trade/Device Name: Diazyme Glycated Serum Protein Enzymatic Assay Kit
Diazyme Glycated Serum Controls
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP, JJX
Dated: July 14, 2004
Received: August 12, 2004

Dear Dr. Yuan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042193

Device Name: Diazyme Glycated Serum Protein Enzymatic Assay Kit

Indications for Use:

Diazyme Glycated Serum Protein Enzymatic Assay Kit in conjunction with Diazyme Glycated Serum Protein single calibrator, are intended for the quantitative determination of glycated serum proteins (fructosamine) in serum. The measurement of glycated serum proteins (fructosamine) is useful for monitoring diabetic patients.

Diazyme Glycated Serum Protein Enzymatic Assay Kit contains a single calibrator. The calibrator is used in the calculation of glycated serum protein concentrations in unknown serum samples.

Diazyme Glycated Serum Protein Enzymatic Assay has controls for normal glycated serum protein level and abnormal glycated serum protein level. The controls are used as reference samples for checking the functionality of the Diazyme Glycated Serum Protein Enzymatic Assay.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042193